Applicant: Ladner et al. Attorney's Docket No.: 10280-140003 / DX/002 CIP 2

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REMARKS

Claims 227-234, 240, 243, and 248-262 are pending in this application. The examiner has withdrawn claims 248-262. Applicants have amended claim 227 without prejudice or disclaimer. Support for the amendment to claim 227 can be found in the application as filed, for example, in Example 3, beginning at page 49 of the specification. No new matter has been added.

Withdrawn Claims 248-262

The Office has withdrawn claims 248-262. At page 2 of the Office Action, the Office states, "claims 249-262 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected Group III." The Office goes on to state

Furthermore, newly submitted claim 248 is also directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 248 contains an undefined linker attached to M13 gene III, which does not fall within the scope of a protein and/or library of proteins.

Applicants respectfully disagree. Elected Group IV is drawn to a "library of a collection of members of a diverse family of peptides." Claim 227 recites (in part) a library comprising a collection of members of a family, the family comprising a diversity of peptides, polypeptides or proteins, which the Office concedes to fall within the elected group. Claims 248-262 all depend (directly or indirectly) from claim 227, and thus, like claim 227, necessarily fall within elected Group IV. Because of their dependency on claim 227, these claims are also drawn to a library comprising a collection of members of a family, the family comprising a diversity of peptides, polypeptides or proteins. It is of no consequence that these dependent claims recite additional elements because they are still drawn to the same elected subject matter.

The Office alleges that claims 249-262 are drawn to non-elected Group III. This cannot be. Non-elected Group III is drawn to a "library of genetic packages." This is not the subject matter of claims 249-262. Rather, claims 249-262 are drawn to a library comprising a collection of members of a family, the family comprising a diversity of peptides, polypeptides or proteins.

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as recited in claim 227. Claims 249-262 merely provide an additional limitation to the elected subject matter, e.g., by specifying how the elected libraries comprising a collection of members of a family are displayed or reciting additional sequences.

Likewise, claim 248 merely specifies that the peptides, polypeptides or proteins of the elected library are linked via a short linker. However, the claim is still drawn to a library comprising a collection of members of a family, the family comprising a diversity of peptides, polypeptides or proteins.

Because claims 248-262 are all drawn to the subject matter of the elected group (Group IV) and depend from claim 227 of the elected group, Applicants respectfully request that claims 248-262 be rejoined and examined in the present application.

35 U.S.C. § 112, First Paragraph

The Office alleges that claims 227-234, 240, and 243 are rejected under 35 U.S.C. § 112, and that Applicants have failed to demonstrate possession of the claimed subject matter. Further, the Office alleges that, "Applicants' current claim read on 'any' library of peptides, polypeptides or proteins. That is, to the extent that Applicants' claimed library no longer represents VH CDR regions such broadened scope represents new matter" (Office Action at pages 3-4).

Applicants disagree with the Office's interpretation of the claimed subject matter. However, in the interest of expediting prosecution, Applicants have amended claim 227 to recite (in part) a library comprising a collection of members of a family, the family comprising a diversity of peptides, polypeptides or proteins, wherein the peptides, polypeptides or proteins each comprise a VH CDR1 and a VHCDR2 and are encoded by DNA sequences comprising sequences encoding the VH CDR1 and the VH CDR2. Thus, the amendments make it clear that the components of the claimed library contain both VH CDR1 and VH CDR2 regions.

Further, Applicants re-iterate that the subject matter recited in the claims is supported by the application as filed. For example, in Figures 10 and 17; at page 51, lines 5-14; page 52, lines 11-14; page 16, lines 27-32; page 14, lines 4-8; page 14, line 29 to page 15, line 3; page 15, lines 5-11: page 35, lines 21-24; page 44, lines 2-3; and page 46, lines 11-12.

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Applicants respectfully request that this rejection be withdrawn, as the claimed subject matter is supported by the application as filed.

35 U.S.C. § 102/103

The Office alleges that claims 227-234, 240, and 243 are anticipated by, or are obvious in light of, Heddle et al. (*Immunology* 29:185-195 (1975); "Heddle"), as evidenced by Roitt et al. (*Immunology* 6th ed., pages 67-70 and 80 (2001); "Roitt").

Applicants disagree. Claim 227 has been amended to more clearly recite that the peptides, polypeptides or proteins of the claimed library comprise a VH CDR1 and a VH CDR2. Further, the peptides, polypeptides or proteins are encoded by DNA sequences comprising sequences encoding (a) the VH CDR1, wherein the VH CDR1 comprises an amino acid sequence according to the formula -X₁-Y-X₂-M-X₃-, wherein X₁, X₂, and X₃ are independently selected from the group consisting of A, D, E, F, G, H, I, K, L, M, N, P, Q, R, S, T, V, W, and Y, and (b) the VH CDR2, wherein the VH CDR2 comprises an amino acid sequence according to the formula X₄-I-X₅-X₆-S-G-G-X₇-T-X₈-Y-A-D-S-V-K-G-, wherein X₄ and X₅ are independently selected from the group consisting of Y, R, W, V, G, and S, X₆ is selected from the group consisting of P and S, and X₇ and X₈ are independently selected from the group consisting of A, D, E, F, G, H, I, K, L, M, N, P, Q, R, S, T, V, W, and Y. Applicants submit that the elements of claim 227 (and its dependencies) are not taught or suggested by the references cited in the Office Action.

Heddle is devoid of any description or suggestion regarding a library comprising a collection of members of a family, the family comprising a diversity of peptides, polypeptides or proteins that contain a VH CDR1 and a VH CDR2 wherein the peptides, polypeptides or proteins are encoded by DNA sequences that comprise sequences encoding the specified VH CDR1 and VH CDR2 sequences. Roitt also lacks any description or suggestion whatsoever of the claimed library of peptides, polypeptides or proteins. As a result, because all of the elements recited in claim 227 are not taught by Heddle or Roitt, claim 227 (and its dependencies claims 228-234, 240, and 243 (and withdrawn claims 248-262)) are novel over both of these references.

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Further, the Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc. (Federal Register, Vol. 72, No. 195, October 10, 2007; page 57528, right column to page 57529, left column; "Guidelines") state:

The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in KSR noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting In re Kahn [441 F.3d 977, 988 (Fed. Cir. 2006)] stated that ""[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."

Thus, the Office must articulate some rational reasoning to support its obviousness rejection.

Applicants submit that the Office has failed to set forth any rational reasoning to establish a *prima facie* case of obviousness against claim 227 and its dependencies claims 228-234, 240, and 243. There is absolutely no teaching or suggestion in Heddle or Roitt to prepare the claimed library comprising a collection of members of a family, the family comprising a diversity of peptides, polypeptides or proteins wherein the peptides, polypeptides or proteins are encoded by DNA sequences that comprise sequences encoding the specified VH CDR1 and VH CDR2 sequences. Applicants respectfully request that the obviousness rejection of claims 227-234, 240, and 243 be withdrawn.

Applicants further submit that withdrawn claims 248-262 are non-obvious.

CONCLUSION

Applicants respectfully submit that all of the pending claims are in condition for allowance, which action is expeditiously requested. Applicants do not concede any positions of the Examiner that are not expressly addressed above, nor do Applicants concede that there are not other good reasons for patentability of the presented claims or other claims.

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No fees are believed to be due. Please apply any charges or credits to deposit account 06-1050, referencing Attorney Docket No. 10280-140003.

Respectfully submitted,

Date: 100/ 8 2007

Fish & Richardson P.C. 225 Franklin Street Boston, MA 02110 Telephone: (617) 542-5070 Facsimile: (617) 542-8906

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Natalie A. Lissy, Ph.D. Reg. No. 59,651